ATTORNEY DOCKET NO. 21108.0023U2
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	)	
	)	
Maquat, LE	)	Art Unit: 1635
	)	
Application No. 10/525,273	)	Examiner: Zara, Jane J
	)	
Int. Filing Date: August 21, 2003	)	Confirmation No. 4987
	)	
For: NONSENSE-MEDIATED MRNA DECAY	)	

RESPONSE TO RESTRICTION REQUIREMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

BALLARD SPAHR ANDREWS &
INGERSOLL, LLP
Customer Number 23859

Sir:

This is in response to the Office Action dated March 14, 2004, wherein restriction of the claims of the above-identified application is required. A Request for Extension of time is included herewith.

The Office Action requires restriction to one of the following two groups of claims:

Group I: Claims 1-13, drawn to methods of treating a disorder in a subject;

Group II: Claims 14-29 and 31-36, drawn to methods of screening for substances that modulate nonsense mediated mRNA (NMD) decay complexes;

Group III: Claim 30, drawn to methods of screening for modulating substances comprising incubating a substances with a stably transfected cell;

Group IV: Claim 37, drawn to methods of screening for modulating substances comprising administering a substance to a system;

Group V: Claim 38, drawn to a method of modulating nonsense mediated mRNA decay activity;

Group VI: Claim 39, drawn to a method of making a substance capable of modulating nonsense mediated mRNA decay activity;

Group VII: Claim 41, drawn to a method of making a substance capable of modulating nonsense mediated mRNA decay activity comprising administering a substance to a system; and

Group VIII: Claims 40, 42-73, drawn to a substances that modulate NMD.

As required in response to the Restriction Requirement, Applicants provisionally elect Group IV (claim 37) with traverse.

Applicants note that while the Office action indicates further election of:

(1) A single mutation with the elected Group (Claim 5, 6);

(2) A single disorder with the elected Group (Claims 2, 3, 4, 7, and 8);

(3) A decrease or increase in NMD with the elected Group (Claims 10, 11, and 14);

(4) A single combination of substances with the elected Group (Claims 15-29); and

(5) A single substance with the elected group (Claims 43-73),

it does not indicate whether such election is required with election of each of Groups I-VIII. Applicants therefore interpret this requirement to be made only if the Group related to the independent claim from which the above claims depend is elected. Thus, as none of the claims are dependent from claim 37, Applicants understand that no further election is required. If, however, the Examiner chooses to rejoin Group III and/or IV with Group II as requested below, Applicants will make the necessary election from items (3) and (4) in response thereto.

The Office Action asserts that "[i]nventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects." However, 37 C.F.R. § 1.475 provides that national stage applications shall relate to one invention or to a group of inventions so linked as to form a single general inventive concept. Such inventions possess unity of invention under PCT Rule 13.1. PCT Rule 13.2, which states:

> ... the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

However, the Office Action does not assert that the groups of inventions are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Applicants assert that in fact all of the claims of Groups I-VIII relate to the special technical feature of substances that modulate nonsense-mediated mRNA decay (NMD) and uses thereof. MPEP 1850 states that "[w]hether or not any particular technical feature makes a "contribution" over the prior art, and therefore constitutes a "special technical feature," should be considered with respect to novelty and inventive step." Applicants respectfully point out that the Examiner has not provided any evidence that any disclosure exists in the art that would destroy the novelty or inventive step of this common technical feature and thereby destroy the single inventive concept. Thus, the Examiner has not met the burden for establishing a lack of unity of invention and the restriction is improper.

Applicants also note that the Office Action incorrectly states that the claims of Group II, Group III, and Group IV involve distinct steps which are not included in the other methods, involve different biological outcomes, require administration of different and distinct compounds and compositions, and involve distinct steps of measurement of different phenomena and phenotypes that not present in the other Groups. Applicants respectfully disagree. For example, claim 14 is directed to

> A method of screening for a substance that modulates [NMD] complex comprising … incubating the substance with the complex, and …assaying for a change in NMD…

and claim 37 is directed to:

> A method of screening for a substance that modulates [NMD] comprising … administering a substance to a system, wherein the system comprises the components essential for NMD activity, and … assaying the effect of the substance on the amount of NMD activity in the system....

As noted on page 19 of the specification "NMD complex" refers to "any combination of one or more of the essential components of NMD in the pioneering round of translation." Thus, the method of claim 37 involves administering a substance to a system comprising NMD complex. Moreover, "system" is defined on page 19 of the specification as "any cell, organism, or in vitro assay or culture … [including] components necessary for NMD activity." Thus, the *in vitro* method of claim 14 and the cellular system of claim 30 are "systems" as defined in the specificaion. Applicants therefore submit that at least the claims of Groups II, III, and IV should be examined together and respectfully request favorable consideration of at least claims 14-37.

A Credit Card Payment authorizing payment in the amount of $1,115.00, representing the fee for a small entity under 37 C.F.R. § 1.17(a)(5) for a Five Month Extension of Time, and a

Request for Extension of Time are hereby enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

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